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510(k) SUMMARY

BIOSCIENCE, INC.
BIOFIX® Biodegradable Meniscus Arrow System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Name of Device and Name/Address of Sponsor

BIOFIX® Biodegradable Meniscus Arrow System

Bioscience, Inc.
279 B Great Valley Parkway
Malvern, PA 19355

Classification Name

Bioabsorbable orthopedic fixation device

Predicate Devices

Davis & Geck Maxon Monofilament Polyglyconate Synthetic Absorbable Surgical Sutures (PMA G840051) (Maxon sutures)

Acufex Microsurgical, Inc. T-Fix Suture Bar (K925573) and implantation instruments (K942442) (T-Fix Meniscus Fixation System)

Intended Use

The BIOFIX® Meniscus Arrow System is intended for arthroscopic fixation of longitudinal vertical meniscus lesions (bucket-handle lesions) located in the vascularized area of the meniscus (*e.g.*, "red-red" and "red-white" area) in conjunction with appropriate immobilization.

Technological Characteristics and Substantial Equivalence

BIOFIX® Meniscus Arrows are bioabsorbable orthopedic fixation devices composed of self-reinforced poly-L-lactide (SR-PLLA). They possess physical and chemical properties necessary for secure fixation of longitudinal vertical meniscus lesions (bucket-handle lesions) located in the vascularized area of the meniscus (*e.g.*, "red-red" and "red-white" area) in combination with suitable immobilization. The surgically implanted BIOFIX® Meniscus Arrows lose strength over 20 to 50 weeks *in vivo*; within a corresponding period of time, the meniscus rupture is healed. The implant material degrades by hydrolysis rather than by enzymatic action. The degradation product is lactic acid, a normal body metabolite, that is readily eliminated as carbon dioxide during respiration.

The BIOFIX® Meniscus Arrow consists of a cylindrical shaft with barbs in one end and a T-shaped head at the other end. The barbs assure that the shaft is kept in place in the capsule and the peripheral part of the meniscus, while the T-shaped head keeps the loose part of the meniscus in close proximity to the periphery. The device has a shaft diameter of 1.1 mm and is available in lengths of 10 mm, 13 mm, and 16 mm. The dimensions of the T-shaped head are 1.0 mm x 1.1 mm x 3.5 mm. A specially designed set of application instruments, made of medical grade stainless steel, are required for implantation of BIOFIX® Meniscus Arrows. The set consists of six cannulae, a blunt obturator a small drill or needle, and a piston.

The BIOFIX® Meniscus Arrow System is substantially equivalent to two predicate devices: (1) Davis & Geck's Maxon sutures, approved under PMA

G840051; and (2) Acufex Microsurgical's T-Fix Suture Bar and implantation instruments (T-Fix Meniscus Fixation System), cleared under K925573 and K942442. The BIOFIX® Meniscus Arrow System is substantially equivalent to these predicate devices in that its intended use is a use subsumed within the broader indication of the Maxon sutures for soft tissue approximation and within the broader indication of the T-Fix Meniscus Fixation System for meniscal repair, and in that BIOFIX® Meniscus Arrows and its predicate devices are designed to stabilize the meniscus during the healing period.

The BIOFIX® Meniscus Arrow System, like the two predicate devices, uses standard arthroscopic portals for implantation. Both the BIOFIX® Meniscus Arrow System and the T-Fix Meniscus Fixation System are implanted with precise delivery instruments. Both BIOFIX® Meniscus Arrows and Maxon sutures are absorbed by the body, unlike the T-Fix device which is permanent unless removal is necessary because of an adverse situation.

BIOFIX® Meniscus Arrows, like the predicate devices, are supplied sterile and require good surgical technique and proper postoperative immobilization.

Although there are some differences in materials and implantation instruments and technique between the BIOFIX® Meniscus Arrows and its predicate devices, no new issues of safety and efficacy have been raised.

Nonclinical and Clinical Testing

Nonclinical Testing

Mechanical testing was carried out to determine the initial separation force between the head and shaft of the arrow and the initial pull-out force of the barbs on the arrow shaft, and these same properties under *in vitro* hydrolytic conditions that simulate the hydrolytic degradation of the BIOFIX® Meniscus Arrow *in vivo*. These results and the results of the clinical study described below demonstrated that the arrows possess sufficient strength for the period needed for healing and stabilization of the fixation site.

Clinical Testing

Arthroscopic fixation of longitudinal vertical meniscus lesions (bucket-handle lesions) with BIOFIX® Meniscus Arrows was compared in a prospective, randomized, controlled trial to inside-out arthroscopic suturing with the Acufex Double Barrel System using Maxon-0 sutures. Patients returned for evaluation at two weeks, five weeks, nine weeks, 12 weeks, six months, and at one year following surgery. Complete healing was defined as healing in the full length of the former rupture, while partial healing was defined as a residual rupture of less than 10 mm in an otherwise stable meniscus.

Thirty-four patients were enrolled in each treatment group. Of the 32 patients in the BIOFIX® Meniscus Arrow group for whom 12 week healing assessment results were available, 26 were found to have healed lesions, three to have partially healed, stable lesions, two to have partially healed, unstable lesions, and one to have an unhealed lesion. Of the 31 patients in the suture group for whom 12 week healing assessment results were available, 17 were found to have healed lesions, seven to have partially healed, stable lesions, two to have partially healed, unstable lesions, and five to have an unhealed lesion. Results were also analyzed for each treatment group by length of tear, distance from joint capsule to lesion, and operative location of meniscal tear. When the "healed" versus "not healed" results were grouped, there was a statistically significant difference in favor of the BIOFIX® Meniscus Arrow group ($p = 0.032$).

Knee function scores were analyzed for each treatment group at the 12 week, six month, and one year visits; scores were comparable in the two groups at each assessment. In addition, patients evaluated their own status at the follow-up visits and rated their status as "excellent," "acceptable," or "unacceptable." There were no significant differences in the number of excellent or acceptable assessments at any visit in the two groups, nor in the number of unacceptable assessments.

There were no deep or superficial infections related to meniscal repair in the BIOFIX® Meniscus Arrow group, nor were there any serious neurological problems. There were two deep infections in the suture group and two cases of superficial infection related to meniscal repair in the suture group; no serious neurological problems were reported in this group.

In summary, BIOFIX® Meniscus Arrows were shown to be at least as good as sutures in the treatment of bucket-handle lesions. In this study, operative time was considerably less, more lesions were healed 12 weeks postoperatively, and there were fewer meniscal repair-related complications in the BIOFIX® Meniscus Arrow group than in the suture group, while functional results were comparable.